-CITE-
10 USC Sec. ***1107*** 01/05/99
-EXPCITE-
TITLE 10 - ARMED FORCES
Subtitle A - General Military Law
PART II - PERSONNEL
CHAPTER 55 - MEDICAL AND DENTAL CARE
-HEAD-
Sec. 1107. Notice of use of an investigational new drug or a drug unapproved for its applied use
-STATUTE-
(a) Notice Required. - (1) Whenever the Secretary of Defense requests or requires a member of the armed forces to receive an investigational new drug or a drug unapproved for its applied use, the Secretary shall provide the member with notice containing the information specified in subsection (d).
(2) The Secretary shall also ensure that health care providers who administer an investigational new drug or a drug unapproved for its applied use, or who are likely to treat members who receive such a drug, receive the information required to be provided under paragraphs (3) and (4) of subsection (d).
(b) Time of Notice. - The notice required to be provided to a member under subsection (a)(1) shall be provided before the investigational new drug or drug unapproved for its applied use is first administered to the member.
(c) Form of Notice. - The notice required under subsection (a)(1) shall be provided in writing.
(d) Content of Notice. - The notice required under subsection (a)(1) shall include the following:
(1) Clear notice that the drug being administered is an investigational new drug or a drug unapproved for its applied use.
(2) The reasons why the investigational new drug or drug unapproved for its applied use is being administered.
(3) Information regarding the possible side effects of the investigational new drug or drug unapproved for its applied use, including any known side effects possible as a result of the interaction of such drug with other drugs or treatments being administered to the members receiving such drug.
(4) Such other information that, as a condition of authorizing the use of the investigational new drug or drug unapproved for its applied use, the Secretary of Health and Human Services may require to be disclosed.
(e) Records of Use. - The Secretary of Defense shall ensure that the medical records of members accurately document -
(1) the receipt by members of any investigational new drug or drug unapproved for its applied use; and
(2) the notice required by subsection (a)(1).
(f) Limitation and Waiver. - (1) In the case of the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation,

the requirement that the member provide prior consent to receive the drug in accordance with the prior consent requirement imposed under section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) may be waived only by the President. The President may grant such a waiver only if the President determines, in writing, that obtaining consent -
(A) is not feasible;
(B) is contrary to the best interests of the member; or
(C) is not in the interests of national security.
(2) In making a determination to waive the prior consent requirement on a ground described in subparagraph (A) or (B) of paragraph (1), the President shall apply the standards and criteria that are set forth in the relevant FDA regulations for a waiver of the prior consent requirement on that ground.
(3) The Secretary of Defense may request the President to waive the prior consent requirement with respect to the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation. With respect to any such administration -
(A) the Secretary may not delegate to any other official the authority to request the President to waive the prior consent requirement for the Department of Defense; and
(B) if the President grants the requested waiver, the Secretary shall submit to the chairman and ranking minority member of each congressional defense committee a notification of the waiver, together with the written determination of the President under paragraph (1) and the Secretary's justification for the request or requirement under subsection (a) for the member to receive the drug covered by the waiver.
(4) In this subsection:
(A) The term ''relevant FDA regulations'' means the regulations promulgated under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)).
(B) The term ''prior consent requirement'' means the requirement included in the relevant FDA regulations pursuant to section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)).
(C) The term ''congressional defense committee'' means each of the following:
(i) The Committee on Armed Services and the Committee on Appropriations of the Senate.
(ii) The Committee on National Security and the Committee on Appropriations of the House of Representatives.
(g) Definitions. - In this section:
(1) The term ''investigational new drug'' means a drug covered by section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)).
(2) The term ''drug unapproved for its applied use'' means a drug administered for a use not described in the approved labeling of the drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

-SOURCE-
(Added Pub. L. 105-85, div. A, title VII, Sec. 766(a), Nov. 18, 1997, 111 Stat. 1827; amended Pub. L. 105-261, div. A, title VII, Sec. 731(a)(1), (b), Oct. 17, 1998, 112 Stat. 2070, 2071.)
-MISC1-
AMENDMENTS
1998 - Subsec. (b). Pub. L. 105-261, Sec. 731(b)(1), struck out '', if practicable, but in no case later than 30 days after the drug is first administered to the member'' after ''administered to the member''.
Subsec. (c). Pub. L. 105-261, Sec. 731(b)(2), struck out ''unless the Secretary of Defense determines that the use of written notice is impractical because of the number of members receiving the investigational new drug or drug unapproved for its applied use, time constraints, or similar reasons. If the Secretary provides notice under subsection (a)(1) in a form other than in writing, the Secretary shall submit to Congress a report describing the notification method used and the reasons for the use of the alternative method'' after ''provided in writing''.
Subsecs. (f), (g). Pub. L. 105-261, Sec. 731(a)(1), added subsec. (f) and redesignated former subsec. (f) as (g).
-CHANGE-
CHANGE OF NAME
Committee on National Security of House of Representatives changed to Committee on Armed Services of House of Representatives by House Resolution No. 5, One Hundred Sixth Congress, Jan. 6, 1999.
-MISC4-
EFFECTIVE DATE OF 1998 AMENDMENT
Pub. L. 105-261, div. A, title VII, Sec. 731(a)(2), Oct. 17, 1998, 112 Stat. 2071, provided that: ''Subsection (f) of section 1107 of title 10, United States Code (as added by paragraph (1)), shall apply to the administration of an investigational new drug or a drug unapproved for its applied use to a member of the Armed Forces in connection with the member's participation in a particular military operation on or after the date of the enactment of this Act (Oct. 17, 1998).''
WAIVERS OF REQUIREMENT FOR PRIOR CONSENT GRANTED BEFORE OCTOBER 17, 1998
Pub. L. 105-261, div. A, title VII, Sec. 731(a)(3), Oct. 17, 1998, 112 Stat. 2071, provided that: ''A waiver of the requirement for prior consent imposed under the regulations required under paragraph (4) of section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) (or under any antecedent provision of law or regulations) that has been granted under that section (or antecedent provision of law or regulations) before the date of the enactment of this Act (Oct. 17, 1998) for the administration of a drug to a member of the Armed Forces in connection with the member's participation in a particular military operation may be applied in that case after that date only if -
''(A) the Secretary of Defense personally determines that the waiver is justifiable on each ground on which the waiver was

granted;
''(B) the President concurs in that determination in writing; and
''(C) the Secretary submits to the chairman and ranking minority member of each congressional committee referred to in section 1107(f)(4)(C) of title 10, United States Code (as added by paragraph (1)) -
''(i) a notification of the waiver;
''(ii) the President's written concurrence; and
''(iii) the Secretary's justification for the request or for the requirement under subsection 1107(a) of such title for the member to receive the drug covered by the waiver.''